4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-2032]

Determination That BUTISOL SODIUM (Butabarbital Sodium) Oral Tablets, 15 Milligrams, 50 Milligrams, and 100 Milligrams, and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products if they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993-0002, 301-796-8363, Stacy.Kane@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as

the “listed drug,” which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is generally known as the “Orange Book.” Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table are no longer being marketed.

Application No.	Drug Name	Active Ingredient(s)	Strength(s)	Dosage Form/Route	Applicant
NDA 000793	BUTISOL SODIUM	Butabarbital Sodium	15 mg; 50 mg; 100 mg	Tablet; Oral	Mylan Specialty, L.P.
NDA 007392	SECONAL SODIUM	Secobarbital Sodium	50 mg/Milliliter (mL)	Injectable; Injection	Eli Lilly and Co.
NDA 012665	VELBAN	Vinblastine Sulfate	10 mg/Vial	Injectable; Injection	Eli Lilly and Co.
NDA 017015	PAVULON	Pancuronium Bromide	1 mg/mL; 2 mg/mL	Injectable; Injection	Schering-Plough Corp.
NDA 017919	ORTHO-NOVUM 1/35-28	Ethinyl Estradiol; Norethindrone	0.035 mg;1 mg	Tablet; Oral-28	Janssen Pharmaceuticals, Inc.
NDA 018554	EULEXIN	Flutamide	125 mg	Capsule; Oral	Schering-Plough Corp.
NDA 019151	RYTHMOL	Propafenone Hydrochloride	150 mg, 225 mg, 300 mg	Tablet; Oral	GlaxoSmithKline
NDA 019579	TERAZOL 7	Terconazole	0.4%	Cream; Vaginal	Janssen Pharmaceuticals, Inc.
NDA 019599	NAFTIN	Naftifine Hydrochloride	1%	Cream; Topical	Sebela Ireland Limited
NDA 019653	ORTHO CYCLEN-28	Ethinyl Estradiol; Norgestimate	0.035 mg; 0.25 mg	Tablet; Oral-28	Janssen Pharmaceuticals, Inc.
NDA 019716	DIPROLENE	Betamethasone Dipropionate	EQ 0.05% Base	Lotion, Augmented; Topical	Merck Sharp & Dohme Corp.
NDA 019964	TERAZOL 3	Terconazole	0.8%	Cream; Vaginal	Janssen Pharmaceuticals, Inc.
NDA 020313	MIACALCIN	Calcitonin Salmon	200 International Units/Spray	Metered Spray; Nasal	Mylan Ireland Limited
NDA 020388	NAVELBINE	Vinorelbine Tartrate	EQ 10 mg Base/mL	Injectable; Injection	Pierre Fabre Medicament
NDA 020413	ZERIT	Stavudine	1 mg/mL	For Solution; Oral	Bristol-Myers Squibb
NDA 020741	PRANDIN	Repaglinide	0.5 mg; 1 mg; 2 mg	Tablet; Oral	Gemini Laboratories, LLC
NDA 020872	CHILDREN'S ALLEGRA ALLERGY	Fexofenadine Hydrochloride	30 mg	Tablet; Oral	Sanofi-Aventis U.S., LLC
NDA 021071	AVANDIA	Rosiglitazone Maleate	EQ 8 mg Base	Tablets; Oral	SB Pharmco Puerto Rico, Inc.

NDA 021235	PROZAC WEEKLY	Fluoxetine Hydrochloride	EQ 90 mg/Base	Delayed-Release Capsules; Oral	Eli Lilly and Co.
NDA 021909	CHILDREN'S ALLEGRA HIVES	Fexofenadine Hydrochloride	30 mg	Tablet, Orally Disintegrating; Oral	Sanofi-Aventis U.S., LLC
NDA 022246	METOZOLV ODT	Metoclopramide Hydrochloride	EQ 5 mg Base	Tablet, Orally Disintegrating; Oral	Bausch Health US, LLC
NDA 022291	PROMACTA	Eltrombopag Olamine	EQ 100 mg Acid	Tablet; Oral	Novartis
NDA 022362	WELCHOL	Colesevelam Hydrochloride	1.875 g/ Packet	For Suspension; Oral	Daiichi Sankyo
NDA 022396	DYLOJECT	Diclofenac Sodium	37.5 mg/mL (37.5 mg/mL)	Solution; Intravenous	Javelin Pharmaceuticals, Inc.
NDA 050368	ILOTYCIN	Erythromycin	0.5%	Ointment; Ophthalmic	Eli Lilly and Co.
NDA 050587	PRIMAXIN	Cilastatin Sodium; Imipenem	EQ 250 mg Base/Vial; 250 mg/Vial	Powder; Intravenous	Merck & Co., Inc.
NDA 201373	CHILDREN'S ALLEGRA HIVES	Fexofenadine Hydrochloride	30 mg/5 mL	Suspension; Oral	Sanofi-Aventis U.S., LLC
NDA 208411	NARCAN	Naloxone Hydrochloride	2 mg/Spray	Spray, Metered; Nasal	Adapt Pharma

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs and ANDAs listed are unaffected by the discontinued marketing of the products subject to those NDAs and ANDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products

should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: October 16, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020-23300 Filed: 10/20/2020 8:45 am; Publication Date: 10/21/2020]